K100278

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510(k) Summary

[as required by 21 CFR 807.92(c)]

APR 30 2010

Submitter	**MAQUET Cardiopulmonary AG** Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person	Katrin Schwenkglenks Phone: 011 49 7478 921 151 Fax: 011 49 7478 921 8667
Date Prepared	January 29, 2010
Device Trade Name	**QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING**
Common/Usual Name	Oxygenator with integrated heat exchanger
Classification Names	Cardiopulmonary bypass oxygenator *(21 CFR 870.4350 – Product Code: DTZ)* Cardiopulmonary bypass heat exchanger *(21 CFR 870.4240 – Product Code: DTR)*
Predicate Devices	D101 KIDS Infant Hollow Fiber Membrane Oxygenator with phosphorylcholine coating (Ph.I.S.I.O. coating), *Sorin Group Italia S.r.l.* (K072091) Quadrox D Diffusion Membrane Oxygenator with BIOLINE COATING, *MAQUET Cardiopulmonary AG* (K071774)

Device Description

The QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING is a blood-gas exchanger with integrated heat exchanger. It is a sterile and non-pyrogenic medical device which is intended for the treatment of pediatric patients.

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Indications for Use

The diffusion membrane oxygenator QUADROX-iD Pediatric is intended for use in an extracorporeal perfusion system. The oxygenator is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.
The utilization period for this device is restricted to six hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Statement of Technical Comparison

The QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING is comparable to the QUADROX D Diffusion Membrane Oxygenator with BIOLINE COATING (art. code BE-HMOD 2000, BEQ-HMOD 2030) from MAQUET Cardiopulmonary AG, K071774, regarding the design, principals of operation, biocompatibility and performance as well as regarding the BIOLINE Coating. The main difference is the size of the oxygenator. The basic elements were downsized to fit the needs of pediatric patients. Thereby priority is given to the preservation of the approved functionality of the oxygenator and to the acquirement of new advantages regarding priming volume, foreign surface and pressure force.
The QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING is also comparable to the D101 Kids Infant Hollow Fiber Oxygenator with Ph.I.S.I.O. Coating, Sorin Group Italia S.r.l., K072091, regarding performance and indications for use.

Non-clinical Testing

The QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING has been tested to and met the requirements of ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing as well as the requirements of ISO 7199 Cardiovascular implants and artificial organs – Blood-gas exchangers (oxygenators).

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Determination of Substantial Equivalence

Evaluation and testing on safety and effectiveness was executed to demonstrate that the QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING described in this submission is substantially equivalent to the QUADROX D Diffusion Membrane Oxygenator with BIOLINE COATING from MAQUET Cardiopulmonary AG (K071774) and to the D101 KIDS Infant Hollow Fiber Membrane Oxygenator with Ph.I.S.I.O. coating from Sorin Group Italia S.r.l. (K072091).

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING is substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 30 2010

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strabe 38
D-72145 Hirrlingen, Germany

Re: K100278
Trade/Device Name: Quadrox-iD Pediatric Diffusion Membrane Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: January 29, 2010
Received: February 1, 2010

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Bahmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100278

Device Name:

QUADROX-iD Pediatric Diffusion Membrane Oxygenator with BIOLINE COATING

Indications for Use:

The diffusion membrane oxygenator QUADROX-iD Pediatric is intended for use in an extracorporeal perfusion system. The oxygenator is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The utilization period for this device is restricted to six hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Nguyen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100278